



## Clinical trial results:

### Imaging of tumour microenvironment in patients with oropharyngeal head and neck squamous cell carcinoma using RGD PET/CT imaging.

#### Summary

EudraCT number	2019-001843-37
Trial protocol	NL
Global end of trial date	01 April 2024

#### Results information

Result version number	v1 (current)
This version publication date	05 June 2025
First version publication date	05 June 2025

#### Trial information

##### Trial identification

Sponsor protocol code	52649
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

##### Sponsors

Sponsor organisation name	Radboud University Medical Center
Sponsor organisation address	Geert Grooteplein Zuid 10, Nijmegen, Netherlands, 6525 GA
Public contact	Department Nuclear Medicine, Radboud University Medical Center, +31 243613651, <a href="mailto:evelein.vangenugten@radboudumc.nl">evelein.vangenugten@radboudumc.nl</a>
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Notes:

##### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	01 May 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 April 2024
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to assess the differences in [68Ga]Ga-RGD2 uptake and CT perfusion parameters between HPV+ HNSCC tumours and HPV- HNSCC tumours in patients who will be treated with chemoradiotherapy. Furthermore, the changes in [68Ga]Ga-RGD2 uptake and CT perfusion parameters in tumours before and during chemoradiotherapy will be investigated.

Protection of trial subjects:

To minimize hospital visits, scans were planned on days of already existing hospital visits needed for standard of care - where possible.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	4
From 65 to 84 years	5



## Subject disposition

### Recruitment

Recruitment details:

All patients that met the inclusion criteria were asked to participate in the trial, and availability of logistics of study visits was checked. If these criteria were met, the patient could participate.

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	9
Number of subjects completed	9

### Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	HPV negative
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Ga RGD
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

bolus of 200 MBQ plusminus 10%

<b>Arm title</b>	HPV positive
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Arm description: -

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Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

bolus of 200 MBQ plusminus 10%

<b>Number of subjects in period 1</b>	HPV negative	HPV positive
Started	4	5
Completed	4	5

## Baseline characteristics

<b>Reporting groups</b>	
Reporting group title	HPV negative
Reporting group description: -	
Reporting group title	HPV positive
Reporting group description: -	

<b>Reporting group values</b>	HPV negative	HPV positive	Total
Number of subjects	4	5	9
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	66.8	61.6	
full range (min-max)	62 to 72	49 to 71	-
Gender categorical Units: Subjects			
Female	1	0	1
Male	3	5	8

## Subject analysis sets

Subject analysis set title	HPV positive
Subject analysis set type	Sub-group analysis

Subject analysis set description:

It is proven that besides more broad carcinogenesis patterns, oropharyngeal carcinomas can develop due to the lingering humane papilloma virus in the throat. This subtype of patients have higher survival rate, but is it still unknown what the exact mechanism is behind these differences in survival. Therefore we aim to compare patients where HPV presence is proven on the tumor tissue with patients where this virus was not detected.

Subject analysis set title	HPV negative
Subject analysis set type	Sub-group analysis

Subject analysis set description:

It is proven that besides more broad carcinogenesis patterns, oropharyngeal carcinomas can develop due to the lingering humane papilloma virus in the throat. This subtype of patients have higher survival rate, but is it still unknown what the exact mechanism is behind these differences in survival. Therefore we aim to compare patients where HPV presence is proven on the tumor tissue with patients where this virus was not detected.

<b>Reporting group values</b>	HPV positive	HPV negative	
Number of subjects	5	4	
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	61.6	66.8	
full range (min-max)	49 to 71	62 to 72	
Gender categorical Units: Subjects			
Female	1	0	
Male	3	5	

## End points

### End points reporting groups

Reporting group title	HPV negative
Reporting group description: -	
Reporting group title	HPV positive
Reporting group description: -	
Subject analysis set title	HPV positive
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
It is proven that besides more broad carcinogenesis patterns, oropharyngeal carcinomas can develop due to the lingering humane papilloma virus in the throat. This subtype of patients have higher survival rate, but is it still unknown what the exact mechanism is behind these differences in survival. Therefore we aim to compare patients where HPV presence is proven on the tumor tissue with patients where this virus was not detected.	
Subject analysis set title	HPV negative
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
It is proven that besides more broad carcinogenesis patterns, oropharyngeal carcinomas can develop due to the lingering humane papilloma virus in the throat. This subtype of patients have higher survival rate, but is it still unknown what the exact mechanism is behind these differences in survival. Therefore we aim to compare patients where HPV presence is proven on the tumor tissue with patients where this virus was not detected.	

### Primary: Uptake of 68Ga-RGD2 in tumor lesions

End point title	Uptake of 68Ga-RGD2 in tumor lesions <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe:	
Measured on the 68Ga-RGD2 PET/CT made pre-treatment	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: For interim analysis we used arithmetic mean and standard deviation. Statistics will be used in the paper to be published	

End point values	HPV positive	HPV negative		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed				
Units: SUV				
arithmetic mean (full range (min-max))	6.1 (4.9 to 8.7)	7.7 (5.4 to 9.9)		

### Statistical analyses

No statistical analyses for this end point

### Primary: CT perfusion paramters

End point title	CT perfusion paramters <sup>[2]</sup>
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End point description:

End point type	Primary
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End point timeframe:

Measured on the CT perfusion scan made pre-treatment

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: For interim analysis we used arithmetic mean and standard deviation. Statistics will be used in the paper to be published

<b>End point values</b>	HPV positive	HPV negative		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed				
Units: perfusion				
arithmetic mean (standard deviation)	11249 ( $\pm$ 1578)	13016 ( $\pm$ 1807)		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:  
within the time frame of patient participation

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Assessment type	Non-systematic
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### Dictionary used

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Dictionary name	CTC
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Dictionary version	5.0
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Frequency threshold for reporting non-serious adverse events: 5 %

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Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There are no (S)AEs as it is a diagnostic IMP

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 October 2020	Reduction of number of scans to speed up inclusion

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
30 March 2020	COVID-19 global pandemic	08 June 2020

Notes:

### Limitations and caveats

None reported